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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,126	12/15/2003	Gregory Plowman	034536-0928	2609

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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,126	PLOWMAN ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 1-16 and 19-28 have been cancelled by Applicant.

Claims 17-18 are pending and are currently under consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17, as written, does not sufficiently distinguish over antibodies, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18 are rejected as vague and indefinite for reciting the terms Aur1 and/or Aur2 as the sole means of identifying the claimed antibodies and corresponding

hybridoma cell lines. The use of laboratory designations to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. For example, Vankayalapati et al. (Molecular Cancer Therapeutics, 2003, 2:283-294.) describe AUR1 as the same protein as aurora1 kinase. Further, Vankayalapati et al. describe AUR2 as aurora2 kinase. Amending the claims to specifically and uniquely identify Aur1 and Aur2 by SEQ ID Nos can obviate the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth an isolated antibody or antibody fragment thereof having specific binding affinity to a polypeptide comprising SEQ ID NO:3 or SEQ ID NO:4 and a hybridoma which produces an antibody having specific binding affinity to SEQ ID NO:3 or SEQ ID NO:4; thus, the written description is not commensurate in scope with the claims which read on antibodies that bind to AUR1 and/or AUR2 or a hybridoma which

produces an antibody having specific binding affinity to an AUR1 and/or AUR2 polypeptide.

The claims are drawn to an isolated antibody or antibody fragment thereof having specific binding affinity to a polypeptide comprising SEQ ID NO:3 or SEQ ID NO:4 and a hybridoma which produces an antibody having specific binding affinity to SEQ ID NO:3 or SEQ ID NO:4. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are broadly inclusive of antibodies that bind to a genus of polypeptides that is defined only by sequence identity.

The specification teaches "By "an AUR1 and/or AUR2 polypeptide" is meant 25 (preferably 30, more preferably 35, most preferably 40) or more contiguous amino acids set fourth in the full length amino acid sequence of SEQ ID NO:3 or SEQ ID NO:4, or a functional derivative therof aas described herein. In certain aspects, polypeptides of 100, 200, 300 or more amino acids are preferred. The AUR1 an/or AUR2 polypeptide can be encoded by a full-length nucleic acid sequence or any portion of the full-length nucleic acid sequence, so as a functional activity of the polypeptide is retained." (see paragraph 15 of PGPUB 2004/0265852).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics

of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is reference to laboratory polypeptide. Further, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated antibody or antibody fragment thereof having specific binding affinity to a polypeptide comprising SEQ ID NO:3 or SEQ ID NO:4 and a hybridoma which produces an antibody having specific binding affinity to SEQ ID NO:3 or SEQ ID NO:4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Niwa et al. (Gene, March 1996, 169:197-201.) in view of Campbell ("Monoclonal

Antibody Technology", Laboratory Techniques in Biochemsity and Molecular Biology, 1984, 13:1-32.).

According to the specification, "By an "AUR1 and/or AUR2 polypeptide" is meant 25 (preferably 30, more preferably 35, most preferably 40) or more contiguous amino acids set forth in full length amino acid sequence of SEQ ID NO:3 or SEQ ID NO:4, or a functional derivative thereof as described herein." (paragraph 15 of PGPUB 2004/0265852, in particular). Niwa et al. teach a sequence that is a 83.3% match, and is 100% identical over a span of >40 amino acids, to SEQ ID NO:3 of the instant specification (figure 1, in particular).

Nihwa et al. do not teach an antibody having specific binding affinity to AUR1 and/or AUR2 polypeptide or a hybridoma cell line which produces an antibody having specific binding affinity to an AUR1 and/or AUR2 polypeptide. However, these deficiencies are made up for in the teachings of Campell.

Campbell teaches (page 29) that is "customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)". Additionally, the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious.

See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a polypeptide sequence encoded by SEQ ID NO:3 for the purposes of generating hybridoma cells that produce monoclonal antibodies that specifically bind to AUR1 and/or AUR2 polypeptide. One would have been motivated to do so because it is conventional in the art to generate monoclonal antibodies using hybridoma cells following the cloning of a gene. Further, one of skill in the art would have a reasonable expectation of success in producing the claimed antibodies and hybridoma cells since the production of antibodies and antibody-producing hybridoma cells are well known and conventional in the art.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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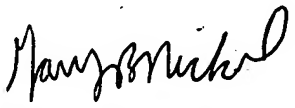

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PRIMARY EXAMINER